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Incyte Holdings Corporation

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INCYTE CORP. and INCYTE HOLDINGS CORP., **Plaintiffs,** **v.** **APOTEX INC.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Incyte Corporation and Incyte Holdings Corporation (together, "Incyte"), by their undersigned attorneys, for their Complaint against Defendant Apotex Inc. ("Apotex") allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*., arising from Apotex's submission of Abbreviated New Drug Application ("ANDA") No. 208869 ("Apotex's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Incyte's Jakafi® (ruxolitinib) drug product, 5 mg, 10 mg, 15 mg,

20 mg, and 25 mg tablets, prior to the expiration of United States Patent Nos. 7,598,257 (the "'257 patent"); 8,415,362 (the "'362 patent"); 8,722,693 (the "'693 patent"); 8,822,481 (the "'481 patent"); and 8,829,013 (the "'013 patent") (collectively, the "patents-in-suit"). The patents-in-suit are owned by Incyte Corporation and/or Incyte Holdings Corporation.

The Parties

2. Plaintiff Incyte Corporation is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

3. Plaintiff Incyte Holdings Corporation is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

4. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

The Patents-in-Suit

5. On October 6, 2009, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '257 patent, entitled, "Heteroaryl substituted pyrrolo[2,3-b]pyridines and pyrrolo[2,3-b]pyrimidines as janus kinase inhibitors." A copy of the '257 patent is attached hereto as Exhibit A.

6. On April 9, 2013, the USPTO duly and lawfully issued the '362 patent, entitled, "Pyrazolyl substituted pyrrolo[2,3-b]pyrimidines as Janus kinase inhibitors." A copy of the '362 patent is attached hereto as Exhibit B.

7. On May 13, 2014, the USPTO duly and lawfully issued the '693 patent, entitled, "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile." A copy of the '693 patent is attached hereto as Exhibit C.

8. On September 2, 2014, the USPTO duly and lawfully issued the '481 patent, entitled, "Salts of the janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-d] pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile." A copy of the '481 patent is attached hereto as Exhibit D.

9. On September 9, 2014, the USPTO duly and lawfully issued the '013 patent, entitled, "Salts of the Janus kinase inhibitor (R)-3-(4-(7H-pyrrolo[2,3-D]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile." A copy of the '013 patent is attached hereto as Exhibit E.

The Jakafi® Drug Product

10. Incyte Corporation holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a) for Jakafi® (ruxolitinib) (NDA No. 202192).

11. The claims of the patents-in-suit cover, *inter alia*, ruxolitinib, pharmaceutical compositions comprising ruxolitinib, methods of using and administering ruxolitinib, ruxolitinib phosphoric acid salt, solid forms of ruxolitinib phosphoric acid salt, methods of using and administering ruxolitinib phosphoric acid salt, and pharmaceutical compositions comprising ruxolitinib phosphoric acid salt.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Jakafi®.

13. The FDA-approved prescribing information for Jakafi® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Jakafi® according to one or more of the methods claimed in the patents-in-suit.

Jurisdiction and Venue

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Apotex by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

16. On information and belief, Apotex purposefully has conducted and continues to conduct business in this Judicial District.

17. On information and belief, Apotex is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

18. This Court has personal jurisdiction over Apotex pursuant to Federal Rule of Civil Procedure 4(k)(2), including because (a) Incyte's claims arise under federal law; (b) Apotex is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex has sufficient contacts with the United States as a whole, including, without limitation, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Apotex satisfies due process.

19. On information and belief, Apotex submitted ANDA No. 208869 seeking FDA approval to engage in the manufacture, use, importation, distribution, offer to sell, and/or sale of the generic drug product that is the subject of Apotex's ANDA ("Apotex's Proposed Products"),

throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

20. On information and belief, this Judicial District is a likely destination for Apotex's Proposed Products.

21. On information and belief, Apotex intends to benefit directly if its ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Apotex's Proposed Products.

22. Apotex has purposefully availed itself of the rights, benefits, and privileges of New Jersey, including by asserting counterclaims in this Court. *See, e.g.*, *GW Research Ltd. v. Teva Pharms., Inc.*, *et al.*, No. 23-3914 (D.N.J.); *Amgen Inc. v. Apotex Inc.*, No. 22-3827 (D.N.J.); *Supernus Pharms., Inc. v. Apotex Inc., et al.*, No. 20-7870 (D.N.J.); *Boehringer Ingelheim Pharms., Inc.*, *et al. v. Apotex Inc., et al.*, No. 18-11350 (D.N.J.); *Patheon Softgels Inc. v. Apotex Inc., et al.*, No. 17-13819 (D.N.J.); *Merck Sharp & Dohme Corp. v. Apotex Inc., et al.*, No. 17-5399 (D.N.J.).

23. Venue is proper in this Judicial District for Apotex pursuant to 28 U.S.C. §§ 1391 and/or 1400(b), including, for example, because Apotex is a company organized and existing under the laws of Canada and may be sued in any judicial district.

Acts Giving Rise To This Suit

24. Pursuant to Section 505 of the FFDCA, Apotex submitted ANDA No. 208869 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products before the patents-in-suit expire.

25. On information and belief, following FDA approval of Apotex's ANDA, Apotex will make, use, sell, or offer to sell Apotex's Proposed Products throughout the United States, and/or import such generic products into the United States.

26. On information and belief, in connection with the submission of ANDA No. 208869 as described above, Apotex provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Apotex's Paragraph IV Certifications"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Apotex's ANDA.

27. Apotex subsequently sent to Incyte written notice of Apotex's Paragraph IV Certifications for the patents-in-suit, alleging that the claims of those patents are invalid and/or will not be infringed by the activities described in Apotex's ANDA. Apotex's written notice to Incyte conveyed that Apotex seeks approval to market Apotex's Proposed Products before the patents-in-suit expire.

Count I: Infringement of the '257 Patent

28. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

29. Apotex's submission of ANDA No. 208869, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products prior to the expiration of the '257 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. There is a justiciable controversy between the parties hereto as to the infringement of the '257 patent.

31. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '257 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

32. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '257 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '257 patent and knowledge that its acts are encouraging infringement.

33. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '257 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that Apotex's Proposed Products are especially adapted for a use that infringes one or more claims of the '257 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

34. Incyte will be substantially and irreparably damaged and harmed if Apotex's infringement of the '257 patent is not enjoined.

35. Incyte does not have an adequate remedy at law.

36. This case is an exceptional one, and Incyte is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '362 Patent

37. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

38. Apotex's submission of ANDA No. 208869, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products prior to the expiration of the '362 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

39. There is a justiciable controversy between the parties hereto as to the infringement of the '362 patent.

40. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '362 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

41. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '362 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '362 patent and knowledge that its acts are encouraging infringement.

42. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '362 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that

Apotex's Proposed Products are especially adapted for a use that infringes one or more claims of the '362 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

43. Incyte will be substantially and irreparably damaged and harmed if Apotex's infringement of the '362 patent is not enjoined.

44. Incyte does not have an adequate remedy at law.

45. This case is an exceptional one, and Incyte is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '693 Patent

46. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

47. Apotex's submission of ANDA No. 208869, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products prior to the expiration of the '693 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

48. There is a justiciable controversy between the parties hereto as to the infringement of the '693 patent.

49. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '693 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

50. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '693 patent under 35 U.S.C. § 271(b) by

making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '693 patent and knowledge that its acts are encouraging infringement.

51. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '693 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that Apotex's Proposed Products are especially adapted for a use that infringes one or more claims of the '693 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

52. Incyte will be substantially and irreparably damaged and harmed if Apotex's infringement of the '693 patent is not enjoined.

53. Incyte does not have an adequate remedy at law.

54. This case is an exceptional one, and Incyte is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '481 Patent

55. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

56. Apotex's submission of ANDA No. 208869, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products prior

to the expiration of the '481 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. There is a justiciable controversy between the parties hereto as to the infringement of the '481 patent.

58. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '481 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

59. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '481 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '481 patent and knowledge that its acts are encouraging infringement.

60. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '481 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that Apotex's Proposed Products are especially adapted for a use that infringes one or more claims of the '481 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

61. Incyte will be substantially and irreparably damaged and harmed if Apotex's infringement of the '481 patent is not enjoined.

62. Incyte does not have an adequate remedy at law.

63. This case is an exceptional one, and Incyte is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '013 Patent

64. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

65. Apotex's submission of ANDA No. 208869, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products prior to the expiration of the '013 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

66. There is a justiciable controversy between the parties hereto as to the infringement of the '013 patent.

67. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '013 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

68. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '013 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '013 patent and knowledge that its acts are encouraging infringement.

69. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '013 patent under 35 U.S.C. § 271(c) by

making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that Apotex's Proposed Products are especially adapted for a use that infringes one or more claims of the '013 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

70. Incyte will be substantially and irreparably damaged and harmed if Apotex's infringement of the '013 patent is not enjoined.

71. Incyte does not have an adequate remedy at law.

72. This case is an exceptional one, and Incyte is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Incyte respectfully request the following relief:

(A) A Judgment that Apotex has infringed the patents-in-suit by submitting ANDA No. 208869 with the accompanying Paragraph IV Certifications and notice to Incyte of same;

(B) A Judgment that Apotex has infringed, and that Apotex's making, using, selling, offering to sell, and/or importing Apotex's Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of FDA approval of ANDA No. 208869 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Incyte is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Apotex and its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, and/or importing Apotex's Proposed Products until after the

expiration of the patents-in-suit, or any later expiration of exclusivity to which Incyte is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Apotex, its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from practicing any of the subject matter claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Incyte is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Apotex's Proposed Products will directly infringe, induce infringement of, and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Apotex, its officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, has committed any acts with respect to the subject matter claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Incyte damages for such acts;

(H) If Apotex, its officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Apotex's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Incyte resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Incyte its attorneys' fees incurred in this action;

(K) A Judgment awarding Incyte its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: March 28, 2024

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: March 28, 2024

By: s/ Charles M. Lizza

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